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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/789,139

02/27/2004

Kevin P. Connors

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EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/789,139 | <b>Applicant(s)</b><br>CONNORS ET AL. |  |
|                              | <b>Examiner</b><br>david shay        | <b>Art Unit</b><br>3769               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on October 2, 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-17,22,33,40-43 and 49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-17,22,33,40-43 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 2, 2008 has been entered.

With regard to the rejection, applicant argues that because of Altshuler et al ('042) teaches a variety of ranges, the fact that the ranges taught by Altshuler et al ('042) overlaps those claimed by applicant, does not necessarily mean that one of ordinary skill in the art would be directed to employ the range claimed by applicant, citing MPEP 2121.03 and 2144.05. Further applicant makes reference to four publications submitted with the instant response asserting that these publications, albeit funded by assignee, show that the particular range of pulse widths "is best suited for tissue shrinkage" when used with the claimed wavelength band. The examiner has reviewed the attached articles, and while these do show good results, this is not the criteria which must be applied to the claimed invention. The submitted evidence must show unexpected results in order to patentably distinguish a narrow range over a broad one. This aside, the examiner must note that references are to be evaluated for what they would teach one of ordinary skill in the art, and they must also be evaluated for what they teach about the level of skill of one of ordinary skill in the art. Clearly the Altshuler et al and Anderson et al references bespeak a thorough and sophisticated understanding of the interaction between skin tissue and the wavelengths to which it is exposed, especially that these interactions, particularly the degree and depth to which the tissue is heated, are affected by the particular wavelengths used as well as other factors such as fluence, etc. Given this understanding of one of ordinary skill in the art, the

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submitted articles do not overcome the prima facie case of obviousness as constructed in the rejections and demonstrated by the level of knowledge of one of ordinary skill in the art with regard to the wavelength dependence of light tissue interactions. However, even if this were not the case, Altshuler et al ('042) specifically teaches applying radiation in the 1100 nm to 1400 nm range for 2 seconds to affect tissue at a depth of 1mm (see paragraph [0093]), thus applicant's claimed parameters are fairly taught by Altshuler et al ('042).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-17, 22, 33, 42, 43, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2004/0093042 to Altshuler et al. ('3042) in view of U.S. Patent Application Publication US 2002/0173780 to Altshuler et al. ('3780) and further in view of U.S. Patent 6,120,497 to Anderson et al. Altshuler et al. '3042 teach a method and apparatus for treating tissue with light above 1050 nm which can be generated by an incandescent source (non-invasive wrinkle removal) in a region at depth by applying optical radiation thereto of a wavelength able to reach the depth of the region and of a

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selected relatively low power for a duration sufficient for the radiation to effect the desired treatment while concurrently cooling tissue above the selected region to protect such tissue (abstract). The irradiation source (Fig. 1, # 1) may be a radiant lamp, a halogen lamp, an incandescent lamp, an arc lamp, a fluorescent lamp, a light emitting diode, a laser (including diode and fiber lasers), the sun or other suitable optical energy source (paragraph 0044). Cooling is provided by a contact plate (Fig. 1, # 8) and may be made out of a suitable heat transfer material, and also, where the plate contacts tissue, of a material having a good optical match with the tissue. Sapphire is disclosed as an example of a suitable material for the plate. In some embodiments, the contact plate may have a high degree of thermal conductivity, for example, to allow cooling of the surface of the tissue by cooling mechanism (paragraph 0050). The irradiation time may vary from approximately 2 seconds to approximately 2 hours (paragraph 0012). The treatment times overlap those claimed and one skilled in the art would use a time appropriate to achieve the desired temperature based on the operating parameters of the radiation source. Cooling may be applied concurrently with the irradiation or prior to irradiation (paragraph 0011). The cooling of the epidermal layer in conjunction with irradiation inherently yields an inverted temperature gradient. Sensors or other monitoring devices may also be embedded in cooling mechanism, for example, to monitor the temperature, or determine the degree of cooling required by tissue, and be manually or electronically controlled (paragraph 0051). A skilled artisan knows that such control may be via a simple timer or feedback mechanism such as a temperature sensor and typically provides for a means of notification that the process has ended. Indicator lights and audible tones are known and obvious. Altshuler et al. '3042 further teach an irradiation wavelength of from 1050 to 1250 nanometers (paragraph

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0010), which is well known to penetrate tissue from about 2-5 millimeters. A filter (Fig. 1, # 3) is included for wavelength selection. Altshuler et al. '3042 do not disclose cooling after termination of the treatment radiation. Altshuler et al. '3780 teach an apparatus and method for irradiating tissue with a cooled waveguide for cooling the tissue before, during and after irradiation. This clearly teaches a predetermined time after irradiation termination or the cooling would continue indefinitely. Neither Altshuler et al. '3042 nor Altshuler et al. '3780 disclose the specific temperature at which collagen shrinks. Anderson et al. teach a method for treating wrinkles with radiation at depths from 100 microns to 1.2 millimeters (overlaps claim depth) using laser or incoherent radiation (abstract). Anderson et al. specifically disclose the known property of collagen to shrink at temperatures from 60°C to 70°C. It would have been obvious to one skilled in the art to continue cooling the tissue following radiation as taught by Altshuler et al. '3780 while heating collagen to a temperature above 60°C as taught by Anderson et al. in the method of Altshuler et al. '3042 to protect the surface tissue during the treatment process and shrink the collagen. The importance of cooling to avoid damage to peripheral area and it is considered obvious to one of skill in the art, and such person would continue cooling to limit such damage. The combination of the known methodologies would clearly yield a predictable result. Both Altshuler et al. references provide a handpiece. To provide switches and indicators necessary for operation on the handpiece is well known and obvious, thus producing a method such as claimed.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2004/0093042 to Altshuler et al. ('3042) in view of U.S. Patent Application Publication US 2002/0173780 to Altshuler et al. ('3780) in view of U.S. Patent

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6,120,497 to Anderson et al. as applied to claim 15 above and further in view of U.S. Patent 5,885,274 to Fullmer et al. The Altshuler et al. and Anderson et al. teachings are discussed above, but do not teach the importance of the temperature of the filament. Fullmer et al. disclose a filament lamp for use in dermatological treatments including the use of a simmer voltage to maintain the temperature of the filament to allow faster rise time of the light pulses and to enhance the short pulses by the filament being in a warm condition (Col. 7, lines 42-45). It would have been obvious to one skilled in the art to use the simmer pulse (long pulse) as taught by Fullmer et al. in the method of Altshuler et al. '3042 in view of Altshuler et al. '3780 in Anderson et al. to improve the efficiency of the light source pulse integrity as suggested by Fullmer et al., thus producing a method such as claimed.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2004/0093042 to Altshuler et al. ('3042) in view of U.S. Patent Application Publication US 2002/0173780 to Altshuler et al. ('3780) in view of U.S. Patent 6,120,497 to Anderson et al. as applied to claim 15 above and further in view of U.S. Patent Application Publication US 2005/0107850 to Vaynberg et al. The Altshuler et al. teachings are discussed above, but do not teach control of the light source using detected light from the source. Vaynberg et al. disclose a method and system for skin rejuvenation by heating collagen (paragraph 0037) using light from a non-coherent source. The light source is controlled using a light sensor (Fig. 1, # 135) that provides feedback to a controller (Fig. 1, # 130) to alter the pulse parameters (Paragraph 0018). It would have been obvious to one skilled in the art to use the optical feedback as taught by Vaynberg et al. in the method of Altshuler et al. '3042 in view of

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Altshuler et al. '3780 in view of Anderson et al. to provide positive control of the treatment parameters, thus producing a method such as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769